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| 10/562,410 | 09/07/2006 | **Calvin B. Harley** | 511/002 | 6086 |

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| EXAMINER | |
|---|---|
| LOVE, TREVOR M | |

| ART UNIT | PAPER NUMBER |
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| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/562,410 | HARLEY ET AL. | |
| | Examiner | Art Unit | |
| | TREVOR M. LOVE | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Acknowledgement is made to Applicant's response filed 12/23/2009.

Claims 1-10 and 18-25 are pending.

Claims 11-17 are cancelled.

Claims 4 and 10 are withdrawn from consideration.

Claims 1 and 19 are currently amended.

Claims 1-3, 5-9, and 18-25 are currently under consideration.

### ***Withdrawn Rejections***

The rejection of claim 17 under 35 U.S.C. 103(a) as being unpatentable over Mousa (U.S. Patent number 6,171,604) in view of Chou (U.S. Patent number 6,855,344) or Chou (U.S. Pre-Grant publication 2003/0108629) as evidenced by Papadopoulos et al (JAOCS), Close (U.S. Pre-Grant publication number 2002/0044977), and Wu (U.S. Patent number 6,696,094) is withdrawn in view of Applicant's cancellation of claim 17.

### New Grounds of Rejection and/or Objection

#### *Claim Objections*

**Claim 18** is objected to for depending from cancelled claim 17. For the purposed of compact prosecution, claim 18 will be interpreted as depending from independent claim 1. Appropriate correction to claim 18, or cancellation of claim 18, is required.

**Rejections Maintained and Made Again**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-3, 5-9, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mousa (U.S. Patent number 6,171,604, Patent issued Jan. 9,**

**2001) in view of Chou (U.S. Patent number 6,855,344, Patent filed Jul. 16, 2002) or Chou (U.S. Pre-Grant publication 2003/0108629, Application filed Jul. 16, 2002) as evidenced by Papadopoulos et al (1991, JAOCS), Close (U.S. Pre-Grant publication number 2002/0044977, Application published Apr. 18, 2002), and Wu (U.S. Patent number 6,696,094, Patent filed Jul. 31, 2002).** This rejection is maintained and made again in view of Applicant's amendment to claims 1 and 19, and Applicant's cancellation of claim 17. Note, for purposes of compact prosecution, claim 18 is being interpreted as depending from independent claim 1.

Mousa teaches the application of honey for topical treatment of the skin, including skin infections (see Abstract and claim 3-5). In one preferred embodiment Mousa teaches that said composition comprises olive oil, glucose sesquiistearate, methyl glucose dioleate, and honey (see column 6, example 11). Olive oil is known to comprise antioxidants (see Papadopoulos, page 671, first column, first paragraph). Glucose sesquiistearate and methyl glucose dioleate are taught by Mousa to be emulsifiers (see column 5, lines 60-62). Honey is known to be an emulsifier in topical compositions (see Close, [0012]-[0013]).

Mousa fails to directly teach that the composition comprises Applicant's elected species cycloastragenol, the amount in which said cycloastragenol is present, or that the composition has the particular telomerase activity or reconfluence under the instantly identified conditions.

Both Chou references teach a composition which can be topical which utilizes extract of Radix Astragali [Huangqi] (see Chou Patent, column 17, lines 31-43 and

column 22, lines 1-5; see Chou PG-pub, [0150] and [0186]), wherein it is evidenced by Wu that a major ingredient of Radix Astragali is cycloastragenol (see Wu, column 6, Table 1). Said Radix Astragali is taught in Chou to be known for relieving skin infections (see Chou Patent, column 15, lines 25-39; see Chou PG-pub, [0135]-[0140]). It is further taught in Chou that in the composition of Chou Radix Astragali is present in an amount such that one of the major ingredients, astragaloside, is present in an amount of 0.365% (see Chou Patent, columns 18-19, Table III; see Chou PG-pub, [0156], Table III).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the extract of Radix Astragali in the invention of Mousa. One would have been motivated to utilize extract of Radix Astragali in the invention of Mousa since Radix Astragali is taught as being useful for the relieving of skin infections, and the composition of Mousa is also taught as being useful for skin infections. It is noted that MPEP 2144.05 states: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). There would be a reasonable expectation of success in the combination since Mousa and both Chou references are teaching compositions that are useful for treating skin infections.

With regard to the limitation that the compound is isolated, it is noted that the Radix Astragali is taught in both Chou references as being useful in the extracted form. One would have been motivated to utilize the extracted form to allow for a more concentrated form of the active ingredients.

With regard to the amount of cycloastragenol present, though both Chou references are silent as to the amount of cycloastragenol which is preferred, both Chou references do teach a preferred amount of Astragaloside, specifically, 0.365%. Given that Astragaloside and cycloastragenol are both evidenced in Wu to be major ingredients of Radix Astragali, it is the position of the Examiner that the 0.365% would be a starting value which one of ordinary skill in the art would look to for the amount of cycloastragenol. Said amount would be readily optimized by adding more or less extracted Radix Astragali. It is noted that MPEP 2144.05 states: "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). Also, it is further noted that MPEP 2144.05 states: "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)".

With regard to the telomerase activity and reconfluence under the instantly identified conditions, it is the position of the Examiner that absent evidence to the

contrary, the composition of Mousa as modified by either Chou reference would necessarily have the same telomerase activity and reconfluence when placed in the conditions instantly identified. Since the composition of Mousa in view of either Chou reference teaches similar if not the same components, it is the position of the Examiner that the properties of the composition would also be similar, if not the same. It is noted that MPEP 2112 states: ""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

*Response to Arguments*

Applicant argues in the response filed 12/23/2009 that there is no motivation to combine the teachings of Mousa with either teaching of Chou. Applicant's argument is not found persuasive since both Mousa and Chou teach compositions which are topical wherein components are known to be useful as skin treatments. Applicant states that "[t]he Chou references or the Wu reference do not teach the use of extracts of *Radix astragali* for topical application. Applicant's argument is not found persuasive since the Chou references clearly teach the composition of Chou, which comprises the extract of *Radix astragali* for topical application (see Chou Patent column 22, line 5, and PG-Pub [0186]). Applicant argues that Mousa teaches away from the combination since "Mousa

states that "it is the active constituents [of honey] that provide the preparation with its therapeutic, cosmetic and nutritional benefits." One of skill would not have any motivation to add any additional ingredients to the honey composition to improve its skin conditioning properties." (See remarks, page 9, third paragraph). Applicant's arguments is not found persuasive since Applicant's statement is directly contrary to the conclusion of *In re Kerkhoven* wherein, referring to *In re Kerkhoven* MPEP 2144.05 states: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). Applicant argues that the Chou references discuss the use of the root and not the extract of *Radix astragali*, Applicant further alleges that the uses are vague and conflicting, and that no description of how the conditions treated by *Radix astragali* are treated. Applicant's argument has been fully considered, and is not found persuasive. Specifically, the Chou references teach the advantages of *Radix astragali* wherein *Radix astragali* can be utilized orally or topically, and Wu provides evidence that a major ingredient of *Radix astragali* is cycloastragenol. Therefore, one would have been motivated to utilize the extract of *Radix astragali* in the composition of Mousa, noting that the other ingredients of the *Radix astragali* would also be present. Specifically, it is noted that though Chou does not directly teach that the cycloastragenol is the

component which effects skin healing, one would have provided the entire extract of *Radix astragali* to provide said effect. It is noted that MPEP 2145 states: "One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)." Several of Applicant's arguments appear to not account for the references being relied upon in combination. One of ordinary skill in the art, beginning with the teachings of Mousa, would have desired the addition of the extract of *Radix astragali* in view of the teachings of Chou. Applicant further argues that Chou fails to teach the instant concentration (0.01-5%). Applicant's argument is not found persuasive since, as set forth above, both Chou references directly teach that the concentration of the active ingredient of *Radix astragali* is 0.365% which falls directly within the claimed range. Applicant further argues that *Radix astragali* does not necessarily comprise cycloastragenol. Applicant's argument is not found persuasive since Wu clearly evidences that cycloastragenol is a major ingredient of *Radix astragali*. Applicant argues that the teachings of both Chou references are directed to inhibiting cell growth in prostate cancer, and therefore, one would not look to the teachings of a reference wherein inhibition of cell growth is of primary importance, when seeking guidance for a skin composition. Applicant's argument is not found persuasive. Specifically, Applicant has not provided any evidence that the *Radix astragali* component contributes in any way to the inhibition of cell growth. Further, one would look to the teaching within the Chou references directed to *Radix astragali* not necessarily to the teachings regarding

each and every additional component, this is especially the case since the Chou references are being relied upon as secondary references rather than primary references. Furthermore, both Chou references directly correlate *Radix astragali* and skin healing. Therefore, Applicant's arguments are not found persuasive.

## ***Conclusion***

No claims allowed. All claims rejected. No claims objected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is

(571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643